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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,090	05/04/2001	Kevin G. Hetzler	P-5263	9400

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,090

Applicant(s)

HETZLER, KEVIN G.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 9-11, 13-17, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui (JP 11152355).

With respect to claims 9 and 14, Mitsui teaches a method for sterilizing pre-filled syringes (page 1, example) including the following: pre-filled syringes (page 8, technical field, lines 9-10) have already been filled with a liquid, heating the pre-filled syringes in an autoclave in the presence of steam to a first temperature greater than 100 degree Celsius (page 8, technical field, lines 28-29) for at least 20 minutes, then sequentially reducing the temperature of the syringe to a second temperature between 80 and less than 100 degree Celsius by maintaining the second temperature for at least 20 minutes (page 7, technical field, lines 55-61).

With respect to claims 10-11, 13, 15-17, and 19-20, Mitsui discloses the following: heating the syringe at the second temperature in a dry atmosphere (page 8, technical field, lines 29-30), heating the syringe in the autoclave to a first temperature between 120 and 130 degree Celsius (page 8, technical field, lines 28-29) and then reducing the temperature to a second temperature and maintaining for at least 30 minutes in a dry atmosphere (page 7, technical field, lines 55-61), second temperature

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is between 80 and 120 degree Celsius (page 7, technical field, lines 55-61), removing the syringes from the autoclave and transferring the syringes to an oven having a relatively dry atmosphere (page 8, technical field, lines 29-31) and maintaining the second temperature between 80 and 120 degree Celsius for at least 40 minutes (page 7, technical field, lines 55-61), and maintaining the second temperature at a relative humidity of less than 50 percent (page 7, technical field, line 58).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-8, 12, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsui (JP 11152355) in view of Liebert et al (U.S.P.N. 5,207,983).

With respect to claim 1, Mitsui teaches a method for sterilizing pre-filled syringes (page 1, example) including the following: heating the pre-filled syringes in an autoclave in the presence of steam to a first temperature greater than 100 degree Celsius (page 8,

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technical field, lines 28-29) for at least 20 minutes, then sequentially reducing the temperature of the syringe to a second temperature of at least 80 degree Celsius for at least 20 minutes (page 7, technical field, lines 55-61). However, Mitsui fails to disclose maintaining the first temperature for at least 30 minutes. Liebert et al teaches that it is known in the art of sterilizing syringes to maintain a temperature of greater than 100 degree Celsius for at least 30 minutes (col.1, lines 30-36). Thus, it would have been obvious to one having ordinary skill in the art to modify Mitsui method by increasing the exposure time of a syringe at the first temperature in order to sterilize the content of the autoclave (Liebert et al, col.1, lines 38-40).

With respect to claims 2-3 and 5-8, the limitations of which have been addressed above with regard to claims 10-11, 13, 15-17, and 19-20.

With respect to claims 4, 12, and 18, Liebert et al discloses that it is known to keep syringes in the autoclave by exposing them to a first temperature and then cooling them (a second temperature) for a specified amount of time (col.1, lines 32-41) such that the cooling step inherently involves cutting off the steam supply and thereby reducing the humidity.

Conclusion

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Jurgens, Jr. et al (U.S.P.N. 4,628,969) and Liebert et al (U.S.P.N. 5,256,154) teach similar concepts in sterilizing syringes using steam.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.
8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.
9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744

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